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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/783,580	02/15/2001	Lawrence E. Cornett	023533-0113	4347

22428 7590 12/22/2003

FOLEY AND LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

PRIEBE, SCOTT DAVID

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 12/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/783,580

Applicant(s)

CORNETT ET AL.

Examiner

Scott D. Priebe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,8-13,15-31,33-35,38 and 44-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,8-13,15-31,33-35,38 and 44-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 20031016.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 10/16/03 has been entered.

The rejection of claims 13, 14, 44-48, and 50 under 35 USC 112, ¶ 1, for lack of an adequate written description of epithelial cell specific promoter is withdrawn in view of Applicant's arguments.

Claim Rejections - 35 USC § 112

Claims 17 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 13, from which claims 17 and 18 depend, has been amended to limit the promoter to either a viral vector (viral) promoter or an epithelial cell specific promoter. Applicant has not indicated how the original specification supports this amendment, as is their burden. See MPEP 714.02, last sentence of the third paragraph from the end and 2163.06 (I) last sentence. The specification (paragraph bridging pages 20-21) generally discusses inducible promoters, such as those inducible by a hormone. However, it does not mention or describe an inducible viral promoter or inducible epithelial cell specific promoter. There is no evidence of record that such promoters, or their use in the claimed method, were contemplated or possessed by Applicant at the time the application was filed, and the original specification would not place such embodiments of the claimed invention in the hands of the public.

Claims 1-5, 8-13, 15-31, 33-35, 38, and 44-57 remain rejected under 35 U.S.C. 112, first paragraph, for the reasons of record set forth in the Office action of 6/7/02, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The second Cornett declaration under 37 CFR 1.132 filed 10/16/03 is insufficient to overcome the rejection of claims 1-5, 8-13, 15-31, 33-35, 38, and 44-57 for lack of an enabling disclosure as set forth in the last Office action. First, the declaration in ¶ 3 refers to Fig. 1 (Exhibit B). This figure was not provided. The declaration as filed was accompanied by a 14 page *curriculum vitae* and a figure labeled FIGURE 2. Second, the evidence presented in the declaration is only peripherally related to the issue at hand, which is whether the claimed method

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can be used to treat asthma, or some other undisclosed airway disease. The declaration in ¶ 3 indicates that the AAV vectors were administered to normal rats, and that only a “modest fall in dynamic airway resistance” was observed, and concluded that the modest fall was likely due to a “modest change in airway size.” The evidence in ¶ 4 simply verifies that some airway cells had been transfected, and expressed the human β_2 AR encoded by the AAV vectors. There is no evidence that the “modest” effect would be therapeutic in the treatment of asthma, and more importantly, that one would be able to transfect airway epithelium in asthmatics to produce even the “modest” effect observed for the normal rats.

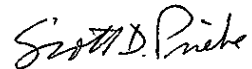
Applicant has still failed to address the known issues in this art as disclosed in Orkin, Factor, and Demoly; for example, that reporter gene studies are not predictive of therapeutic success, that asthmatic lung presents unsolved impediments to vectors delivery and was deemed highly unpredictable both before and after the time the instant invention was made. Orkin makes very clear that one each disease presents its own challenges that must be overcome. Factor and Demoly describe hurdles specific to treating airway diseases, such as asthma, which the instant specification neither accounts for nor teaches how to overcome.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (703) 308-7310. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read "Scott D. Priebe". The signature is written in a cursive, flowing style.

Scott D. Priebe
Primary Examiner
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